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| 10/523,854 | 02/07/2005 | Soon Keun Lee | 930086-2007 | 4420 |

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EXAMINER

WINSTON, RANDALL O

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| ART UNIT | PAPER NUMBER |
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1655

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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/523,854 | Applicant(s) LEE ET AL. | |
| | Examiner Randall Winston | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) 5, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>0205</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-4 and 7 and the election of species of *Canavalia gladiata* with traverse in its response to the restriction requirement of 06/14/2007 is acknowledged. The traversal is based on the grounds that is respectfully submitted that the criteria listed in MPEP 803 have not been met in this case, as no showing has been made that an undue burden would be placed on the Examiner. Moreover, Applicant argues the present invention is not anticipated by Niazi, which is related to a composition containing *Coptis chinensis* as the only extract and therefore constitutes a special technical feature. Furthermore, Applicant argues that the Species Election should be withdrawn, as the MPEP itself indicates that search and examination of plants are few in number do not constitute a serious burden.

Applicant's argument is not found persuasive because, as Examiner explained in the previous restriction requirement of 04/10/2007, group I and group II lack unity of invention. Although Applicant argues the present invention is not anticipated by Niazi, which is related to a composition containing *Coptis chinensis* as the only extract and therefore constitutes special technical feature, Applicant argument is not found persuasive because the special technical feature is well known in the art and lacks novelty because the special technical feature is a topical formulation comprising an extract from *Coptis chinensis* (see, e.g. Group I, claim 1). Niazi (US 6419963, see e.g. column 7 lines 39-45) teaches a topical formulation comprising an extract from *Coptis chinensis*. Thus, since the groups lack unity of invention and the groups do not share a

special technical feature, searching two independent and distinct groups would place an undue on the Examiner.

Moreover, although Applicant argues that the Species Election should be withdrawn, as the MPEP itself indicates that search and examination of plants are few in number do not constitute a serious burden, Applicant argument is not found persuasive because each of the recited claimed plant species are distinct plant species because the claimed plant species are of a different structure which requires a different search for each structure. Thus, the claimed plant species do not share a special technical feature with each other.

The restriction requirement is still deemed proper and is therefore made final.

Please note that the newly recited method of preparation claims of 5, 13 and 14 are of an independent and distinct invention of what applicant elected in applicant's response to the restriction and election of species requirement of 06/14/2007. Since applicant elected group I (i.e. claims 1-4 and 7), a formulation, on 06/14/2007, the method of preparation claims of claims 5, 13, and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 1-4, 7 and newly added depended formulation claims 10-12 and the election of species of a *Canavalia gladiata* will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite because of the term "*Cavalia gladiata*." The above term appears to be misspelled. The correct term should be *Canavalia gladiata*. Correction is required.

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a topical formulation for treating acne comprising extracts obtained from *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis*, the specification does not enable any person skilled in the art to prepare a topical formulation for preventing acne comprising extracts obtained from *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis*.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the

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art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a topical formulation for preventing acne comprising extracts obtained from *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis*. Please note the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has only demonstrated in the experiment section on pages 7-34 of the specification, a topical formulation for treating acne comprising extracts obtained from *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis*. Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a topical formulation for preventing acne comprising extracts obtained from *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis*.

Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to prepare a topical formulation for preventing acne comprising extracts obtained from *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto (JP 409143087 A, see abstract).

Applicant claims a topical formulation comprising an extract obtained from the elected species of *Canavalia gladiata*.

Yamamoto anticipates the claimed invention because Yamamoto teaches a topical formulation comprising an extract obtained from the elected species of *Canavalia gladiata* (see, e.g. abstract). Therefore, the reference is deemed to anticipate the claimed invention.

Please note, the intended use of the above claimed apparatus (i.e. to detect changes in pressure) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-4, 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakasaya (JP 2001089346 A of Derwent Acc NO 2001-324724, see abstract) in view of Sugihara et al. (JP 355127317 A, see abstract) and Basu et al. (US 20020025348).

Applicant claims topical formulation comprising extracts obtained from the elected species of *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis* in various amounts.

Wakasaya teaches a formulation comprising an extract obtained from the elected species of *Canavalia gladiata* (i.e. sword beans)(see, e.g. abstract) administered to a subject to treat inflammation disorders. Wakasaya does not expressly teach the combination of *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis* administered to a subject to treat inflammation disorders (see, e.g. abstract).

Sugihara beneficially teaches *Biota orientalis* extracts externally administered to a subject treats inflammation disorders (see, e.g. abstract).

Basu beneficially teaches *Coptis chinensis* extracts externally administered to a subject treats inflammation disorders (see, e.g. entire patent including abstract, paragraph 21 and claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Wakasaya's formulation to include the claimed active ingredients of *Biota orientalis* and *Coptis chinensis* as taught by Sugihara and Basu within Wakasaya's formulation teachings because the above combined reference would create the claimed invention of claims a topical formulation comprising

extracts obtained from the elected species of *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis* to treat inflammation disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat inflammation disorders), in order to form a third composition to used for the same purpose..." Furthermore, the adjustment of other conventional working conditions (e.g. the claimed active ingredients within various amounts within the claimed formulation and the substitution of one form of the formulation for another), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.


Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER